1648

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:			
Applicant:	**KLEINSCHMIDT, Jürgen WOBUS, Christiane KERN, Andrea**	**Docket No.:**	**4121-123**
Application No.:	**09/830,663**	**Examiner:**	**S. A. Foley**
Filing Date:	**October 16, 2001**	**Group Art Unit:**	**1648**
Title:	**ANTIBODIES BINDING TO THE AAV CAPSID, ANTIBODIES MODIFYING CYTOTROPISM, METHOD FOR TARGETED GENE TRANSFER**	**Customer No.**	**23448**

EXPRESS MAIL CERTIFICATE

I hereby certify that I am mailing the attached documents to the Commissioner for Patents on the date specified, in an envelope addressed to the Commissioner for Patents, Mail Stop Non-Fee Amendment, P. O. Box 1450, Alexandria., VA 22313-1450 and Express Mailed under the provisions of 37 CFR 1.10.

Katrina Holland

Katrina Holland

October 15, 2003
Date

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Express Mail Label Number

RESPONSE TO SEPTEMBER 15, 2003 OFFICE ACTION IN U.S. PATENT APPLICATION NO. 09/830,663

Commissioner for Patents
Mail Stop Non-Fee Amendment
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

In the Office Action dated September 15, 2003, Examiner Foley imposed a restriction requirement under 35 U.S.C. §121 against claims 1-12 and required that an election be made between one of the following groups:

> Group I, claims 1-8, drawn to a monoclonal antibody;
> Group II, claim 9, drawn to a hybridoma;
> Group III, claims 10 and 11, drawn to an AAV vector; and
> Group IV, claim 12, drawn to a process for targeted genetic transfer.

Applicant traverses such a restriction requirement and submits that the product of Group I and it use in additional products and methods of Group II-IV are not patentably distinct from each other because one having a method of using the instantly claimed product of claims 1-8 and 10-11 would obviously have to have the products for including in gene therapy. Further the AAV vector of claims 10 and 11 include the product of claims 1-8. Claim 9 is basically a structure used for making the product of claims 1-8. Thus, the inclusion of the product claims of 1-8 and the use or making of this antibody in a single application is confirmed —indeed, it is mandated— by virtue of the fact that the description requirements of 35 U.S.C. §112 compel disclosure of different aspects of the invention in the one application.

In addition, the courts have recognized that it is in the public interest to permit an applicant to claim several aspects of his/her invention together in one application, as the applicant has done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved. *In re Kuehl,* 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973).

This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications that are filed to prosecute claims that the Office held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent

issued thereon, does not provide comfort to an applicant against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, *Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.,* 784 F.2d 351, 355, 228 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in *Gerber Garment Technology Inc. v. Lectra Systems Inc.*, 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement.

Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest, the Office is not to require restriction in cases, such as the present application, wherein various aspects of a unitary invention are claimed.

In view of the foregoing discussion, reconsideration for the withdrawal of the requirement for restriction is courteously requested. **In the event the requirement is adhered to, applicant provisionally elects with traverse, the invention of Group I (claims 1-8) reciting the monoclonal antibody for further examination on the merits. Further, applicant provisionally select, with traverse, the species "folate" with the understanding that if a generic claim is held to be allowable all species will be found allowable.**

In accordance with Office guidelines recited in MPEP Section 821.04, elected product claims found to recite patentable subject matter **may be rejoined with the provisionally withdrawn method of use type claims** and examined in this one application provided the method of use claims recite the product found to be patentable during examination of the elected invention. In the event the product claim 1-8 are found to recite patentable subject matter, non-elected method claims should be taken up for examination.

Fees Payable

No fee is due for entry of this response. If nonetheless it is determined that any additional fee or charge is properly payable, the same hereby is authorized to be charged to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

Respectfully submitted,

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